REMARKS

Claims 10 and 19 have been amended, claim 13 has been canceled. Claims 10-12 and 14-20 currently are pending.

Claims 19 is rejected under 35 USC § 112, second paragraph. The examiner stated that claim 19 recites the limitation "other conventional tableting excipients" in the last line of the claim but this limitation makes it unclear what particular tableting excipients are being claimed, since conventions change with time. In response, applicants amend the claim by deleting "conventional."

Claims 10, 15, and 18-20 are rejected under 35 USC § 102(b) as being anticipated by Staniforth et al. (US 5,741,524). The examiner stated: "Staniforth teaches an improved excipient for tableting. The excipient can be wet granulated and dried using known methods such as tray drying, spray drying, etc., (col. 2, lines 14-23), though it is preferred that the product is spray dried (col. 14, lines 28-32). The excipient includes a non-ionic surface active agent. The excipient further includes dyes and other tableting agents (col. 12, lines 11-40). The particles of the resultant free-flowing powder are between 10 and 1000 microns (col. 14, lines 51-60). These limitations render the claims anticipated." (Office action, 9/28/03, page 3, item 4)

Applicants amend claim 10 by incorporating the limitations of claim 13. Now as amended Staniforth et al. do not teach each and every element of the rejected claims. Anticipation can only be established by a single prior art reference which discloses each and every element of the claimed invention. *RCA Corp. v. Applied Digital Data Systems, Inc.,* 730 F.2d 1440, 1444, 221 USPQ, 385, 388 (Fed. Cir. 1984).

Claims 11-14, 16 and 17 are rejected under 35 USC § 103(a) as being unpatentable over Staniforth et al. (US 5,741,524) in combination with Khan et al. (US 4,806,358) and Sutton et al. (US 5,993,805). The examiner stated that: " taking the art into consideration it would have been obvious to a skilled artisan to combine the teachings of Staniforth, Sutton and Kahn. Staniforth would have provided the process for making the free-flowing excipient with improved compressibility properties. A skilled artisan would have been motivated to substitute the microcrystalline cellulose of Staniforth with the PVP of either Kahn or Sutton since both compounds are known for their compression properties and preferred use in tableting."

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP § 2143.

The examiner has not addressed the issue of whether there would be a reasonable expectation of success in combining the reference. This is a component of establishing a *prima facie* case of obviousness. The examiner has not done so, therefore a *prima facie* case of obviousness has not been established.

Furthermore, applicants believe the examiner has not adequately set forth required suggestion or motivation to modify/combine the cited reference. Therefore, applicants believe the examiner has not set forth a *prima facie* case of obviousness.

The problem addressed by the presently claimed invention concerns the difficulty of incorporating larger amounts of liquid or semisolid surfactants. Due to the waxy nature of such surfactants the processability of the formulations can cause problems, because the formulations might get sticky.

The problem Staniforth et al. seek to solve is the use of high amounts of microcrystalline cellulose in a formulation, because the loss of compressability of microcrystalline cellulose when used in wet granulation has long been considered a problem (see, col. 3, lines 50-54, and col. 4, lines 35-43). To solve this problem, Staniforth et al. combine the microcrystalline cellulose with a compressibility augmenting agent such as preferably silicon dioxide or a surfactant with a HLB>10, preferably SDS.

The examiner argues that since the single components are known from Sutton and Khan it would be obvious to substitute the components of Sutton and Kahn into the process taught by Staniforth with an expected result of a modified PVP excipient with improved compressibility. This argument misses the point regarding the problem addressed by the present invention. First, the presently claimed process is not directed to improving the compressibility of PVP, but to finding an improved method for handling larger amounts of liquid or semisolid surfactants. Second, the problem underlying Staniforth et al.'s process is caused by the specific surface properties of microcrystalline cellulose. According to Staniforth et al., an improving agent of compressibility such as for a surfactant inhibits the interaction between adjacent cellulose surfaces (see col. 10, lines 1-31). In other words, the technical effects and

results described in Staniforth et al. are linked to the specific properties of microcrystalline cellulose. Therefore, a skilled person trying to find an improved method for combining higher amounts of certain surfactants with water-soluble PVP will not consider the process taught by Staniforth because Staniforth's process completely depends on the properties of water-insoluble microcrystalline cellulose and its surface properties. Motivation to modify/combine Staniforth et al., Kahn et al., and Sutton et al., therefore does not exist.

For the reasons expressed above, it is urged that the prior art references cited by the examiner either singly or in combination fail to anticipate or suggest the present invention as defined by the amended claims. Accordingly, a *prima facie* case of obviousness has not been established by the examiner, and the rejection under 35 USC § 103 should be withdrawn.

A check in the amount of $420.00 is attached to cover the required two month extension fee.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such account.

Respectfully submitted,
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COMPLETE LISTING OF ALL CLAIMS IN THE APPLICATION

1-9 (canceled).

10. (currently amended) A process for producing the excipient adapted for use in a solid pharmaceutical dosage form, wherein said excipient is in the form of a free-flowing powder and consists essentially of a pharmaceutically acceptable polymer and from 10 to 50% by weight, based on the total weight of said excipient, of a liquid or semisolid solubilizing surface-active substance, wherein the polymer in the excipient is a homo- or copolymer of N-vinylpyrrolidone; which comprises either spray-drying a solution comprising the surface-active substance and the pharmaceutically acceptable polymer, or processing the polymer and the surface-active substance in an extruder to obtain a homogeneous melt and subsequently converting the melt into the free-flowing powder.

11. (previously presented) The process according to claim 10, wherein the excipient comprises a surface-active substance which has a drop point in the range from 20 to 40°C.

12. (previously presented) The process according to claim 10, wherein the excipient comprises a surface-active substance which has an HLB of from 10 to 15.

13. (canceled)

14. (previously presented) The process according to claim 10, wherein the excipient comprises from 15 to 40% by weight of the surface-active substance.

15. (previously presented) The process according to claim 10, wherein the excipient comprises ethoxylated sorbitan fatty acid esters as surface-active substances.

16. (previously presented) The process according to claim 10, wherein the excipient comprises the products of the reaction of ethylene oxide with castor oil, hydrogenated castor oil or with 12-hydroxystearic acid as surface active substance.

17. (previously presented) The process according to claim 10, wherein the excipient comprises from 20 to 30% by weight of the surface-active substances.

18. (previously presented) The process according to claim 10, wherein the excipient is in the form of a free-flowing powder of particles having a particle size of from 10 to 1000 µ.

19. (currently amended) The process according to claim 10, wherein the excipient consists of the polymer and the surface-active substance and optionally one or more ingredients selected from the group consisting of flow regulators, dyes, mold release agents, fats, waxes, disintegrants, bulking agents and other ~~conventional~~ tableting excipients.

20. (previously presented) The process according to claim 10, wherein the surface-active substance of the excipient is a non-ionic compound.